EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

REBUTTAL DECLARATION OF CHRISTY M. BORAAS ALSLEBEN, M.D., M.P.H. IN SUPPORT OF PLAINTIFFS' AMENDED MOTION FOR A PRELIMINARY INJUNCTION

I, Christy M. Boraas Alsleben, M.D., M.P.H., declare as follows:

1. I submit this rebuttal declaration in further support of the Amended Motion for a Preliminary Injunction that Plaintiffs Planned Parenthood South Atlantic ("PPSAT") and Dr. Beverly Gray filed to block two components of North Carolina Session Law 2023-14 ("S.B. 20") (codified as amended by Session Law 2023-65 ("H.B. 190") at N.C. Gen. Stat. art. 1I, Ch. 90 (the "Act")), which bans abortion after twelve weeks of pregnancy with narrow exceptions.

2. I previously submitted a declaration in this case, which I executed on July 24, 2023. Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. in Supp. of Pls.' Am. Mot.

for a Prelim. Inj. ("First Boraas Decl."), DE 49-2. That declaration described my qualifications and experience as a board-certified obstetrician/gynecologist (OB/GYN) and Complex Family Planning physician, an abortion provider at the University of Minnesota Medical Center, M Health Fairview Women's Clinic, Whole Woman's Health Twin Cities, and Planned Parenthood North Central States, as well as an educator, consultant, and published author in the field of obstetrics and gynecology.

3. Like the opinions in my original declaration, the opinions in this rebuttal declaration are based on my education, clinical training, experience as a practicing physician, regular review of medical research in my field, and regular attendance and presentation at professional conferences, including conferences for abortion providers. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this declaration.

4. I have reviewed the declarations submitted by Monique Chireau Wubbenhorst, M.D., M.P.H. and Susan Bane, M.D., Ph.D. Nothing in these declarations alters the conclusions I reached or the opinions I expressed in my prior declaration. I am submitting this rebuttal declaration to respond to certain of the statements and opinions expressed in the declarations I reviewed and to offer additional information about the Hospitalization Requirement and the IUP Documentation Requirement. I also disagree with the inflammatory and misleading language used throughout Drs. Wubbenhorst's and Bane's declarations. The fact that I do not address every statement or issue raised in their declarations does not suggest that I agree with them.

5. I have reviewed the rebuttal declaration of Dr. Katherine Farris, also submitted in further support of Plaintiffs' Amended Motion for a Preliminary Injunction. I agree with Dr. Farris's statements and opinions asserted in her rebuttal declaration.

Abortion is Safe and Essential Health Care

6. Abortion is a critical component of reproductive health care, and it is also one of the safest medical procedures in the United States. The American Medical Association (AMA), the largest general medical association in the country, and the American College of Obstetricians and Gynecologists (ACOG), the largest association of OB/GYN specialists, issue ethical guidance that recognizes abortion's important place within health care.[1] In fact, ACOG has affirmed that access to safe, legal abortion is not only important but necessary: "Women *require* access to safe, legal abortion."[2] These organizations recognize the difficult medical decisions sometimes required in reproductive health care, balancing various forms of benefits and harms and the importance of individual autonomy. Drs. Wubbenhorst's and Bane's assertions to the contrary undermine the compassion, empathy, and humanity of abortion providers, and function only to further stigmatize abortion care and alienate patients and providers.

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[1] *See, e.g.*, Br. of Amici Curiae Am. Coll. of Obstetricians & Gynecologists & the Am. Med. Ass'n in Supp. Of Pls.-Appellees & in Supp. of Affirmance at 2, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583 (5th Cir. 2014) (No. 13-51008) ("Access to safe and legal abortion is an important aspect of women's health care.").

[2] ACOG, *Comm. Op. No. 613, Increasing Access To Abortion*, 124 Obstetrics & Gynecology 1060, 1061 (2014) (emphasis added).

7. Intervenors' experts rely on a host of inappropriate conclusions from low quality and/or outdated research to support their conclusions, much of which (1) does not involve second trimester abortion; (2) studied patients in an international context not generalizable to the United States[3]; (3) does not reflect contemporary abortion practice[4]; or (4) suffers from other limitations, such as organizational biases,[5] that render it unreliable. Their approach to summarizing research omits nationally representative, high quality, U.S.-based research and draws conclusions based on conjecture which is not an accepted practice in the field of medicine or in the provision of evidence-based medical care.

8. Dr. Wubbenhorst and Dr. Bane characterize abortion as an unsafe, risky procedure, but the objective fact is that abortion is extremely safe. Leading, reputable, mainstream medical authorities agree, and an abundance of literature supports,[6] that both medication abortion and procedural abortion are two of the safest procedures in medical practice,[7] carry a low risk of complications, and a very low risk of complications requiring

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[3] *See, e.g.*, Declaration of Susan Bane, M.D., Ph.D. ("Bane Decl."), DE 65-3 ¶ 33, (citing a study assessing medication abortion in Finland, Mexico, and South Africa).

[4] *See, e.g.*, Declaration of Monique Chireau Wubbenhorst, M.D., M.P.H ("Wubbenhorst Decl."), DE 65-1 ¶ 39, (citing study that reported on data from 1972-78).

[5] *See, e.g.*, Wubbenhorst Decl. ¶¶ 9-10 (citing the American Association of Pro-Life Obstetricians and Gynecologists' criticisms of credible studies).

[6] *See, e.g.*, Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 217 (2012); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); Nat'l Acads. Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*, at 77-78 (2018), available at http://nap.edu/24950 [hereinafter "Nat'l Acads."].

[7] Nat'l Acads., *supra* note 6, at 77 ("The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective.").

hospitalization, "stand[ing] in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services."[8] Major complications including those requiring hospitalization, surgery, or blood transfusion, occur in only 0.23% of outpatient abortions.[9]

9. As to medication abortion specifically, the National Academies of Sciences, Engineering, and Medicine—a body of esteemed experts that was established by Congress to provide independent, objective expert analysis and advice to the nation to inform public policy—have explained that "[t]he risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs [nonsteroidal anti-inflammatory drugs]," such as ibuprofen and aspirin.[10] Dr. Wubbenhorst takes issue with the assertion that medication abortion is substantially safer than Tylenol and Viagra, and claims that it is untrue because medication abortion "carries a black box warning." Wubbenhorst Decl. ¶¶ 91-95, 119-26.

10. This argument is misleading at best. First, a black box warning is not the sole indicator of a medication's safety. Indeed, commonly purchased over the counter medications such as Aleve, Advil, and Motrin have black box warnings.[11]

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[8] *Id.*

[9] Upadhyay (2015), *supra* note 6, at 181; *see also* Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med. 1, 1 (2018).

[10] Nat'l Acads., *supra* note 6, at 79.

[11] ThienLy Neal, *What Does an FDA Black Box Warning Mean?*, GoodRx (Oct. 12, 2021), https://www.goodrx.com/healthcare-access/medication-education/fda-black-box-warning.

11. A 2018 report by the National Healthcare Cost and Utilization Project found the rate of hospital stays involving adverse drug reactions caused by antibiotics and similar medications, including aspirin, Tylenol, and Viagra, was 151.5 per 10,000 hospital stays, or 1.515 percent.[12] In contrast, according to the FDA, serious adverse events following medication abortion—including death, hospitalization, serious infection, and bleeding requiring transfusion—among mifepristone patients are "exceedingly rare, generally far below 0.1% for any individual adverse event."[13]

12. Dr. Wubbenhorst's suggestion that complications related to medication abortion are underreported to the FDA demonstrates her unfamiliarity with the FDA's regulation of medication abortion and how it monitors prescription drug safety more broadly. Wubbenhorst Decl. ¶¶ 91-95. She ignores that for fifteen years—from mifepristone's approval in 2000 until March 2016—the FDA specifically required that all mifepristone prescribers comprehensively report any serious adverse events associated with mifepristone to the drug manufacturer, and the manufacturer was then required to report all such events to the FDA. This mandatory reporting, imposed as part of the FDA's Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, included any hospitalizations, transfusions, serious infections, death, or "[o]ther serious and unexpected

[12] Audrey J. Weiss et al., *Adverse Drug Events in U.S. Hospitals, 2010 Versus 2014*, Agency for Healthcare Rsch. & Quality, at 4 (2018); *see also* Advancing New Standards in Reprod. Health, Univ. of Cal. S.F., *Analysis of Medication Abortion Risk and the FDA report, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"* (2019).

[13] Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Medical Review(s)* U.S. Food & Drug Admin. 1, 47 (2016).

adverse events" associated with mifepristone, as well as ongoing pregnancies.[14] In 2016, the FDA's scientific review team lifted the REMS requirement that all serious adverse events associated with mifepristone be specially reported, explaining that the "FDA has received such reports for 15 years, and it has determined that the safety profile of Mifeprex is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely."[15] And, after reviewing those 15 years of comprehensive data, the FDA concluded that serious adverse events associated with mifepristone are "exceedingly rare."[16] In other words, the FDA's rigorous data collection for mifepristone far exceeds its data collection for most prescription drugs and aligns with the extensive body of high-quality research confirming that mifepristone is extremely safe.

13. The studies that Dr. Wubbenhorst and Dr. Bane reference in support of their claims that abortion has a high complication rate have serious limitations. For example, Dr. Wubbenhorst cites multiple studies from Finland by Gissler, et al., to support the argument that death rates are higher after abortion compared to childbirth up to 1 year. Wubbenhorst Decl. ¶ 183. However, this old study reported on pregnancy-associated mortality, defined as death while pregnant or within one year from the end of pregnancy, regardless of cause. The conclusions reached by Gissler et al. are thus flawed and unreliable because they include "all-cause mortality," such as homicide and accidental deaths, for

[14] Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Risk Assessment and Risk Mitigation Review(s)*, U.S. Food & Drug Admin. 1, 10 (2016).

[15] Ctr. for Drug Evaluation & Rsch., Medical Review, *supra* note 13, at 8.

[16] *Id.* at 47.

which abortion cannot logically be the "cause."[17] To argue otherwise would require reliance on illogical correlations. For example, it would be inappropriate to claim that abortion "caused" a patient's death if they died in a car accident months after the procedure. Additionally, the CDC has robust data on deaths attributable to abortion in the U.S. The CDC concluded that the "national case-fatality rate for legal induced abortion for 2013-2019 was 0.43 deaths [] per 100,000 reported legal abortions."[18]

14. In addition, both cite a 2009 study by Niinimäki et al., Wubbenhorst Decl. ¶¶ 32-35; Bane Decl. ¶ 35, but that study included evaluations of medication abortion regimens that have never been used in the United States.[19] More critically, the Niinimäki study (1) was based on a Finnish health registry that coded all follow-up visits as "complications" regardless of the degree of concern; and (2) inappropriately reported "hemorrhage" as all patient reports of heavy bleeding, even if they were within the expected range for medication abortion and did not require treatment.[20] In response to criticism on these points, the authors themselves acknowledged that in the records they

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[17] Mika Gissler et al., *Pregnancy Associated Deaths in Finland 1987-1994: Definition Problems and Benefits of Record Linkage*, 76 Acta Obstetricia et Gynecologia Scandinavica 651 (1997): Mika Gissler et al., *Pregnancy-Associated Mortality After Birth, Spontaneous Abortion, or Induced Abortion in Finland 1987-2000*, 190 Am. J. Obstetrics & Gynecology 422 (2004).

[18] Katherine Kortsmit et al., *Abortion Surveillance—United States, 2020*, 71 Morbidity & Mortality Wkly. Rep. 1, 1, 6 (2022).

[19] Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 796 (2009).

[20] Mary Fjerstad et al., *Letters to the Editor: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010); Niinimäki et al., *supra* note 19, at 799-800.

used, "many of the 'complications' are not really such, but rather concerns or adverse events that bring women back to the health care system. . . . [The] [r]ate of serious, 'real' complications is rare and rather similar between [procedural] and medical abortion."[21]

Abortion is Safer than Carrying a Pregnancy to Term and Giving Birth

15. Contrary to the Intervenors' experts' assertions, *see, e.g.*, Wubbenhorst Decl. ¶¶ 167-72, 179-85, abortion is much safer than carrying a pregnancy to term and childbirth.[22] As Dr. Farris highlighted in her first declaration (DE 49-1 ("First Farris Decl.") at ¶ 33-34) the United States has the highest maternal mortality rate among high-income countries,[23] and in 2021 alone, 1,205 people died of pregnancy-related causes in the U.S.[24] In 2021, the maternal mortality rate increased 40 percent from the previous year,[25] making the rate in the U.S. ten times higher than the estimated rate in other high-income countries.[26] And while the maternal mortality rate in the U.S. has significantly increased, the same has not been true for abortions. Leading researchers have found that

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[21] Fjerstad, *supra* note 20, at 660.

[22] Raymond & Grimes, *supra* note 6, at 217.

[23] Dr. Wubbenhorst uses data from studies in Finland to support her claim that "death rates [were] 4 times higher after abortion compared to childbirth," however this comparison is not appropriate given the United States' uniquely high maternal mortality and morbidity rates. *See* Wubbenhorst Decl. ¶ 183; *see also* Bane Decl. ¶ 33 (citing studies from Finland and other countries besides the U.S.).

[24] Selena Simmons-Duffin & Carmel Wroth, *Maternal Deaths in the U.S. Spiked in 2021, CDC Reports*, NPR (Mar. 16, 2023), https://www.npr.org/sections/health-shots/2023/03/16/1163786037/maternal-deaths-in-the-u-s-spiked-in-2021-cdc-reports#:~:text=The%20U.S.%20rate%20for%202021,deaths%20per%20100%2C000%20in%202020.

[25] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Nat'l Ctr. for Health Stats.: Health E-Stats, at 1 (2023).

[26] Selena Simmons-Duffin & Carmel Wroth, *supra* note 24.

legal abortion is approximately 12-14 times safer than continuing a pregnancy through to childbirth.[27]

16. A 2015 study by Upadhyay and colleagues tracked any complications the study population experienced and confirmed that the complication rate for abortions is much lower than that for childbirth.[28] The study's authors examined billing data from a one-year period for women insured under California's Medicaid service, which covers abortion care.[29] The authors identified patients who obtained an abortion covered by California Medicaid through their policy number, including those who were treated for complications within six weeks of the abortion, either at the facility providing abortion care or an emergency department. They concluded that the rate of complication resulting from abortion was 2.11 percent, which includes both major complications (defined as necessitating hospitalization, surgery, or blood transfusion) and minor complications (all non-major adverse events) for all abortion methods in the first trimester, second trimester or later.[30] The majority of complications were minor.[31] For major complications the rate was 0.23 percent.[32] By comparison, the rate of severe complications from childbirth is 144

[27] Raymond & Grimes, *supra* note 6, at 216-17, 217 fig. 1; Nat'l Acads., *supra* note 6, at 37, 75 tbls. 2-4, 77-78.

[28] Upadhyay (2015), s*upra* note 6.

[29] *Id.* at 177.

[30] *Id.* at 179.

[31] *Id.* at 181.

[32] *Id.* at 179-81.

in 10,000, or 1.4 percent.[33] The study concluded that the abortion "complication rate is much lower than that found during childbirth and comparable to that found in the literature, even when [emergency department] visits are included and there is no loss to follow-up."[34]

17. Maternal mortality is not the only risk presented by pregnancy and birth. Every year, an estimated 50-60,000 women in the U.S. experience severe maternal morbidity,[35] or "unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health,"[36] and this rate has been on the rise over the last few decades.[37] Every pregnancy-related complication (such as hemorrhage, infection, and injury to other organs) is more common among people having live births than among those having abortions.[38]

18. Patients who carry their pregnancies to term may also face a multitude of pregnancy-related complications in the antenatal period, including gestational

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[33] *Reproductive Health: Severe Maternal Morbidity*, CDC, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.htm (last visited Aug. 16, 2023).

[34] Upadhyay (2015), s*upra* note 6, at 181.

[35] William M. Callaghan et al., *Severe Maternal Morbidity Among Delivery and Postpartum Hospitalizations in the United States*, 120 Obstetrics & Gynecology 1029, 1034 (2012).

[36] *Severe Maternal Morbidity in the United States*, CDC, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html (last visited Aug. 16, 2023).

[37] *Rates in Severe Morbidity Indicators per 10,000 Delivery Hospitalizations, 1993–2014*, CDC, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.htm (last visited Aug. 16, 2023).

[38] Raymond & Grimes, *supra* note 6, at 216, 217 fig.1.

hypertension, gestational diabetes, infection, preeclampsia, and depression and anxiety.[39] Pregnancy-related complications are unsurprisingly more common among patients who ultimately give birth than those who have an abortion, since pregnancies ending in abortion are substantially shorter than those ending in childbirth and thus entail less time for pregnancy-related problems to occur or progress.[40]

19. Meanwhile, although the risks associated with abortion increase with gestational age (as Intervenors' experts point out), because they are very low to begin with, abortion remains a very safe procedure even later in the second trimester.[41]

20. Moreover, the salient point from these studies is that once someone has decided to have an abortion, they should not face delays because there are increased risks associated with delaying the procedure and continuing the pregnancy. Therefore, obstacles to obtaining abortion care, like those challenged in this case, can cause patients avoidable harm.

Assertions that Alleged Reporting Deficiencies Compromise Data on Abortion Complications and Maternal Mortality are Without Merit

21. Drs. Wubbenhorst and Bane argue that abortion-related deaths and complications are subject to undercounting and underreporting, but this view is not supported by credible evidence. Further, they do not explain how underreporting of the

[39] *What Are Some Common Complications of Pregnancy?*, Nat'l Insts. of Health, https://www.nichd.nih.gov/health/topics/pregnancy/conditioninfo/complications (last accessed Aug. 16, 2023).

[40] Raymond & Grimes, *supra* note 6, at 216-17.

[41] Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998–2010*, 126 Obstetrics & Gynecology 258, 262-63 (2015).

kind they suggest casts doubt on the consensus finding that abortion is less likely to end in complications and death than carrying a pregnancy to term.

22. Intervenors' experts' criticism of the Centers for Disease Control and Prevention's (CDC) data on abortion and abortion-related morbidity, on the theory that there is no comprehensive national data on the occurrence of complications from abortion, is misplaced. *See* Wubbenhorst Decl. ¶¶ 96-104; Bane Decl. ¶¶ 30-31. Importantly, there is also no national reporting requirement for non-mortality complications of pregnancy.

23. The CDC calculates the number of abortions and abortion-related deaths as part of its Pregnancy Mortality Surveillance System, which defines a pregnancy-related death as "a death while pregnant or within 1 year of the end of pregnancy from any cause related to or aggravated by the pregnancy"—a definition that includes both childbirth-related deaths and abortion-related deaths.[42]

[42] *Pregnancy Mortality Surveillance System*, CDC, https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm (last accessed Aug. 16, 2023). The CDC has monitored abortion-related deaths through its Pregnancy Mortality Surveillance System since 1987 using both voluntary reporting by states and other means including "state vital records; media reports, including computerized searches of full text newspaper and other print media databases; and individual case reports by public health agencies, including maternal mortality review committees, health care providers and provider organizations, private citizens, and citizen groups. For each death that possibly is related to abortion, CDC requests clinical records and autopsy reports. Two medical epidemiologists independently review these reports to determine the cause of death and whether the death was abortion related. Discrepancies are discussed and resolved by consensus. Each death is categorized by abortion type as legal induced, illegal induced, spontaneous, or unknown type." Tara C. Jatlaoui et al., *Surveillance Summaries: Abortion Surveillance — United States, 2015*, 67 Morbidity & Mortality Wkly. Rep. 1, 5 (2018).

24. Moreover, the CDC does not rely solely on voluntary reporting by states to generate this data, as Intervenors' experts suggest; it uses death records, linked birth records, fetal death records, and "additional available data from all fifty states, New York City, and Washington, DC."[43] And although the CDC does rely on voluntary reporting to calculate the total number of abortions performed each year, the vast majority of the central health agencies asked to report this data do so.[44] For instance, in 2020, the CDC "request[ed] abortion data from the central health agencies of the 50 states, the District of Columbia, and New York City," and "a total of 49 reporting areas" agreed to provide it.[45]

Intervenors' Experts' Opinions Regarding the Long-term Consequences of Abortion are Not Aligned with Medical Consensus

25. According to the National Academies of Science, Engineering, and Medicine, much of the published literature on abortion's long-term effects on future childbearing and pregnancy outcomes, risk of breast cancer, and adverse mental health outcomes "fails to meet scientific standards for rigorous, unbiased research."[46] The National Academies identified high quality research in these areas and concluded that

[43] CDC, *supra* note 42. Dr. Wubbenhorst is wrong to suggest that research based on Finnish death certificates is a more appropriate basis for calculating mortality rates in the United States. *See* Wubbenhorst Decl. ¶ 171. As the National Academies of Sciences, Engineering, and Medicine concluded, "no clear conclusions regarding the association between abortion and long-term mortality can be drawn from" those studies. Nat'l Acads., *supra* note 6, at 152.

[44] Kortsmit, *supra* note 18, at 1 (2022).

[45] *Id.*

[46] Nat'l Acads., *supra* note 6, at 152.

having an abortion does not increase the risk of preterm birth, breast cancer, or mental health concerns such as depression and anxiety.[47]

26. The Intervenors' experts largely disregard the National Academies report and official positions of professional organizations with specialized expertise that guide the work of OB/GYNs, including abortion providers. Instead, they focus on what they describe as serious data limitations in this area of study, while incorrectly arguing that abortion is uniquely dangerous in the field of obstetrics and gynecology, and medicine more generally. *See, e.g.*, Wubbenhorst Decl. ¶¶ 137-42. In so doing, they overlook high-quality research in the U.S. that refutes many of their critiques.

27. Dr. Bane claims that a prior abortion causes an increased risk of future preterm birth. Bane Decl. ¶¶ 37-38. However, past research is conflicting on any possible link between induced abortion and subsequent preterm birth. Many of these studies are national registry-based making it difficult to assess other confounding variables—factors that may increase both preterm birth and the need for induced abortion. Thus, ACOG has noted that a single induced abortion does not lead to future infertility but has not published guidance stating that induced abortion increases the risk of preterm birth. Additionally, the CDC does not list prior induced abortion as a risk factor for preterm birth. In its report on the quality and safety of abortion care, the National Academies assessed five studies that

[47] *Id.* at 153.

met their inclusion criteria for rigorous, high quality research and concluded that "having an abortion does not increase a woman's risk of . . . preterm birth."[48]

28. Dr. Wubbenhorst and Dr. Bane also opine that there are several studies showing that abortion leads to mental health issues. *See, e.g.*, Wubbenhorst Decl. ¶¶ 51-55; Bane Decl. ¶¶ 39-40. But these opinions rely on methodologically flawed research, including multiple studies by Priscilla Coleman, whose work has been repeatedly discredited by the scientific community.[49]

29. The American Psychological Association has emphatically rejected the notion that abortion is associated with adverse mental health outcomes—on the contrary, *restricting access* to abortion care is associated with worse mental health outcomes.[50] In the Turnaway Study, researchers assessed outcomes for patients who were able to obtain abortions versus those who wanted but could not access abortion care. Patients who had abortions were no more likely to report negative emotions or suicidal thoughts than those who could not obtain an abortion. Rather, patients who could not access an abortion reported more anxiety and stress, lower self-esteem, and lower life satisfaction than

[48] *Id.* at 9, 139-46.

[49] *E.g.*, Julia R. Steinberg et al., *Fatal Flaws in a Recent Meta-Analysis on Abortion and Mental Health*, 86 Contraception 430 (2012); Ellie Kincaid, *Article that Critiqued High-Profile Abortion Study Retracted*, Retraction Watch (Dec. 29, 2022), https://retractionwatch.com/2022/12/29/article-that-critiqued-high-profile-abortion-study-retracted/.

[50] Zara Abrams, *The Facts About Abortion and Mental Health*, Am. Psych. Ass'n, https://www.apa.org/monitor/2022/09/news-facts-abortion-mental-health (last updated Apr. 21, 2023).

patients who were able to obtain an abortion.[51] The APA Task Force on Mental Health and Abortion reached a similar conclusion, finding no greater risk of mental health problems among women who had abortions, including for those patients who chose to terminate a pregnancy because of a fetal anomaly.[52]

Procedural Abortions Can be Safely Provided in Outpatient Facilities

30. As I detailed in my first declaration, the vast majority of procedural abortions can be safely provided in an outpatient facility, and therefore there is no reason to categorically require that all abortions after the twelfth week of pregnancy in cases of rape, incest, or life-limiting fetal anomaly occur in a hospital. *See* First Boraas Decl. ¶ 39.

31. In my first declaration, I highlighted the fact that throughout the country, legal abortions are safely and routinely performed in doctors' offices and outpatient health center settings, and only 3% of abortions are performed in hospitals in the U.S. annually.[53] First Boraas Decl. ¶ 32. There are many reasons that patients justifiably prefer abortions in outpatient centers including shorter appointments, lower costs, sedation options, and

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[51] Corinne H. Rocca et al., *Emotions and Decision Rightness Over Five Years Following an Abortion: An Examination of Decision Difficulty and Abortion Stigma*, 248 Soc. Sci. & Med. 112704 (2020); M. Antonia Biggs et al., *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion*, 74(2) JAMA Psychiatry 169 (2017); *The Mental Health Impact of Receiving vs. Being Denied a Wanted Abortion,* Advancing New Standards in Reprod. Health (2018).

[52] Brenda Major et al., *Report of the APA Task Force on Mental Health and Abortion*, Am. Psych. Ass'n (2008).

[53] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 134 tbl. 3 (2022).

treatment from staff and medical professionals with more experience providing abortions. *See* First Boraas Decl. ¶ 38.

32. Furthermore, while outpatient providers in North Carolina can provide procedural abortions at eleven weeks of pregnancy under the Act, they are not allowed to perform the same procedure at thirteen weeks of pregnancy. There is no difference in the technique or type of risks of an aspiration abortion at the eleventh week of pregnancy versus the thirteenth week of pregnancy.

33. Intervenors' experts describe certain complications that can arise as a result of an abortion after 12 weeks, but for the majority of patients such complications—which are exceedingly rare, as described above—can be treated in the outpatient clinic where the abortion was performed. In my experience, outpatient facilities are well-equipped to treat moderate bleeding, cervical lacerations or tears, and infections.

34. As I described in my first declaration, for patients with certain rare pre-existing conditions that markedly increase the risk of blood loss, such as placenta accreta spectrum disorder, or that require advanced monitoring during anesthesia such as cardiomyopathy or pulmonary hypertension, a hospital abortion may be favorable so that the provider has immediate access to blood products should a transfusion be needed. *See* First Boraas Decl. ¶ 39. In my experience, many times such patients will often seek a hospital abortion in the first instance because of their condition and the associated risks. But more importantly, these conditions are rare and there is no reason to require *all* patients

after 12 weeks to have abortions in hospitals so that these few patients may do so. It is the role of the physician to determine if hospital-based care is required in these rare cases.

35. No medical procedure is entirely risk free. As with many other types of procedures performed in outpatient settings, complications (though rare) may arise during an abortion which outpatient clinics are either well-equipped to treat, or have a protocol to ensure safe transfer to an emergency department. I understand from Dr. Farris's rebuttal declaration that PPSAT has such a protocol for safe transfer.

36. Dr. Bane claims that performing abortions in a hospital "prevents the need for transfer from an outpatient clinic to the nearest hospital facility should complications arise during the surgery, reducing the time for women to receive life-saving interventions." Bane Decl. ¶ 51; *see also* Wubbenhorst Decl. ¶ 216. But this is not necessarily the case. In my experience, transferring a patient between departments within the same hospital can vary greatly depending on the size of the hospital and where each department is located. For example, the operating room where patients are able to access abortion care may be in a different building on a medical campus than the desired unit for postoperative care, such as a surgical intensive care unit.

37. Intervenors' experts claim that hospitals are better equipped than outpatient facilities to support patients who have experienced sexual violence, abuse, or trafficking, but in my experience this too is not always the case. *See* Wubbenhorst Decl. ¶¶ 304, 307; *see also* Bane Decl. ¶ 52. Many providers of reproductive care, including outpatient providers like PPSAT, as I understand from Dr. Farris's rebuttal declaration, receive

training in order to identify patients who are victims of abuse or trafficking, and who have been coerced into either seeking an abortion or continuing a pregnancy, and help direct them to resources where they can receive support.

38. In my experience, not all physicians and staff employed at a hospital receive this type of training. Therefore, staff at the outpatient centers are often better trained to support patients who have experienced abuse, trafficking, or coercion.

39. Further, Dr. Wubbenhorst's statements regarding the instance and impact of coercion surrounding a person's decision to seek abortion are unsupported. *See* Wubbenhorst Decl. ¶ 291. Dr. Wubbenhorst assumes coercion is unidirectional—that people experience coercion only as an effort to force them to choose abortion. In reality, reproductive coercion takes many forms, including pressuring a person to become pregnant and carry a pregnancy to term or to have an abortion, pressuring or coercing a person to have sex, and threatening to leave a relationship if someone does not get pregnant.[54] While most people seeking abortion do not experience coercion, those who do may need extra support and a safe environment to discuss their experiences and options. I understand that PPSAT screens every patient for abortion coercion. Coercion screening is also required at the Planned Parenthood center where I provide care, and I understand it is a requirement that all Planned Parenthood providers ensure that patients considering abortion are not subjected to duress or to coercion of any kind.

[54] ACOG, *Committee Opinion No. 554: Reproductive & Sexual Coercion*, 121 Obstetrics & Gynecology 411, 411 (2013).

40. The Turnaway Study examined patients' experiences with abortion and unintended pregnancy in the U.S., and researchers found that among 954 participants, only one respondent used language that indicated overt pressure from their partner to get an abortion.[55] On the other hand, patients reporting intimate partner violence were more than three times as likely to identify their partner as a reason for wanting an abortion compared to patients not reporting intimate partner violence.[56] But those identifying an abusive partner as a reason for seeking an abortion reported that they were choosing abortion not because their partner was coercing them to do so. Rather, they perceived an abortion as their best option to end the abusive relationship.[57]

41. Intervenors' experts also claim that hospitals have more resources to support patients who have received fetal anomaly diagnoses. *See* Wubbenhorst Decl. ¶¶ 309-26; *see also* Bane Decl. ¶ 52. However, many times, the doctors providing the abortion are not the same doctors diagnosing the fetal anomaly. If the diagnosing doctor is not able to perform the abortion themselves, they may refer the patient to an outpatient provider like PPSAT. Normally, by the time I see a patient who is seeking an abortion due to a life-limiting fetal anomaly, the patient has already received detailed information about the fetal

[55] *See* Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020) (The Turnaway Study studied patients from 21 states over 5 years).

[56] *Id.*

[57] Karuna S. Chibber et al., *The Role of Intimate Partners in Women's Reasons For Seeking Abortion*, 24 Women's Health Issues e131 (2014).

diagnosis and discussed their options with the provider who made the diagnosis and/or their obstetrician, and made the decision to have an abortion.

42. For instance, when I see patients seeking an abortion after receiving a fetal diagnosis from their perinatologist, their records reflect extensive patient education about the diagnosis, the prognosis, and options, including continuing the pregnancy, giving birth, and seeking perinatal hospice care. These patients have already made the extremely personal decision to terminate their pregnancy, and for the majority of these patients their abortion may be safely performed in an outpatient setting.

Medication Abortion is Safe and Effective for Patients with Pregnancies of Unknown Location

43. The Protocol (as defined in my first declaration, First Boraas Decl. ¶ 47) that I, PPSAT, and many other medical institutions use to safely provide medication abortion to patients with pregnancies of unknown location very early in their pregnancy has been shown to be safe and effective, both in research studies and in my daily practice.

44. Intervenors' experts' criticisms mischaracterize the Protocol and are reductive. Dr. Bane states that I and Dr. Farris "claim that HCG levels alone can be used to diagnose an ectopic [pregnancy]." Bane Decl. ¶ 62. This is not true. Dr. Farris and I described a Protocol in which multiple factors, including a detailed conversation with the patient to screen for ectopic pregnancy risks, combined with hCG testing, ultrasonography, and follow up conversations with the patient, are used to determine whether the patient is high- or low-risk for an ectopic pregnancy. First Boraas Decl. ¶ 47. While serial hCG levels are certainly an important factor, they are not the only factor.

45. Dr. Bane also criticizes the Protocol because "approximately one half of women accurately recall their last menstrual period (LMP)," Bane Decl. ¶ 55, implying that providers are making ectopic determinations based on incomplete information from the patients themselves. Her criticism again ignores the multifaceted nature of the Protocol, which does not rely on LMP alone to assess a patient's risk for ectopic pregnancy.

46. As stated in my first declaration, clinicians at both hospitals and outpatient health centers routinely provide detailed counseling and conduct a symptom assessment to identify patients at risk for ectopic pregnancies, including by considering known risk factors, symptoms, and prior and current health history—all of which can be assessed by a detailed conversation with the patient.[58] First Boraas Decl. ¶ 49.

47. When I conduct ectopic screening without ultrasound, I ask patients about their last menstrual cycle (date, timing, regularity, amount of bleeding and cramping, similarity to their regular menstrual cycle, presence of moliminal symptoms); whether they have had a prior ectopic pregnancy, or had treatment and/or hospitalization for pelvic inflammatory disease, or prior tubal sterilization; whether they were using hormonal birth control, an intrauterine device, or oral emergency contraception when they became

[58] *See, e.g.*, Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 British J. Obstetrics & Gynaecology 1464, 1466 (2021) (explaining that patients "were offered a consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made," which included assessing whether "they had a low risk of ectopic pregnancy"); *see also* Upadhyay, Christy M. Boraas et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 J. Am. Med. Ass'n Internal Med. 482 (2022).

pregnant; whether they have had a pregnancy recently and the outcome of that pregnancy; and whether they are experiencing any symptoms such as abdominal or pelvic pain and/or bleeding that was not typical for a menstrual cycle. I do not rely on one single piece of information to make my assessment.

48. Dr. Wubbenhorst criticizes the St. Paul Study[59] (as defined in my first declaration, First Boraas Decl. ¶ 44), claiming that the rates of loss to follow up were "very high" and thus "no conclusions can be drawn related to risk for complications." Wubbenhorst Decl. ¶ 359. However, the loss to follow up rates of the St. Paul Study are consistent with those documented in abortion care literature and a known general limitation of retrospective research studies. In my experience, patients who experience problems do return for care, making the most likely outcome for those who do not follow up a successful, uncomplicated abortion. Furthermore, in my experience of using the Protocol to administer medication abortion in cases of pregnancies of unknown location, I have seen firsthand that it is a safe and patient-centered practice.

49. Dr. Wubbenhorst also criticizes the Goldberg study,[60] claiming that practitioners took too long to diagnose the pregnancy location for patients that initially presented with a pregnancy of unknown location. *See* Wubbenhorst Decl. ¶ 388. However, because these patients were seeking medical intervention at earlier gestational ages than

[59] Karen Borchert, Christy Boraas et al., *Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study*, 122 Contraception 109980 (2023).

[60] Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics & Gynecology 771, 778 (2022).

most pregnant people do, the Protocol actually led to *earlier* exclusion of ectopic pregnancy than waiting to see whether an intrauterine pregnancy could be diagnosed by ultrasound.[61] Both the St. Paul Study and the Goldberg study showed that early medication abortion is safe for patients that have pregnancies of unknown location who have been screened and determined to be low risk for an ectopic pregnancy.

50. Intervenors' experts incorrectly imply that mifepristone is harmful to patients who have an ectopic pregnancy or who are miscarrying. *See* Wubbenhorst Decl. ¶¶ 246-63 (stating that because ectopic pregnancy is listed as a contraindication on the mifepristone product labeling, it therefore must be ruled out before using mifepristone); *see also* Bane Decl. ¶ 61. However, although mifepristone is not FDA approved for the *treatment* of an ectopic pregnancy (and therefore, is listed as a contraindication), a patient with an ectopic pregnancy who takes mifepristone will not be directly harmed by the medication. Likewise, a patient who is experiencing a miscarriage will not be directly harmed by mifepristone. Although the patient will not be harmed, it is important to identify a patient who has an ectopic pregnancy or is miscarrying, which is why the Protocol includes a robust screening process and emphasizes close surveillance and follow up with each patient. Additionally, the medication regimen of mifepristone and misoprostol is the evidence-based therapy for medical management of miscarriage.

51. Research has shown that the incidence of ectopic pregnancy diagnosis following medication abortion is extremely low (0.02 percent), indicating that pretreatment

[61] *Id.*

screening methods are highly successful.[62] Further, there is no evidence to suggest that medication abortion treatment leads to unusual complications for women with ectopic pregnancies.[63]

52. Dr. Bane also criticizes PPSAT's off-label use of mifepristone through 77 days of pregnancy, Bane Decl. ¶ 54, but ignores the fact that the Act *permits* medication abortion "during the first 12 weeks of a woman's pregnancy." Section 90-21.81B(2). What's more, off-label drug use is common in the medical field, and the off-label usage of mifepristone has been shown to be safe at more advanced gestations than that approved by the FDA.[64] I understand that Plaintiffs provide first-trimester medication abortion through 77 days, which is a safe and common evidence-based practice which I offer to my patients as well.[65]

53. Dr. Bane further criticizes the Protocol, stating that a "woman with an ectopic pregnancy may actually confuse the pain and bleeding of a ruptured ectopic pregnancy with the severe pain and bleeding experienced by chemical abortion drugs." Bane Decl. ¶ 61. In my experience, this is extremely unlikely because generally patients with ectopic

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[62] Caitlin Shannon et al., *Ectopic Pregnancy & Medical Abortion*, 104 Obstetrics & Gynecology 161, 161 (2004).

[63] *Id.*

[64] ACOG, *Medication Abortion Up to 70 Days of Gestation* (reaffirmed 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[65] *See, e.g.*, Ilana G. Dzuba et al., *A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review*, 102 Contraception 104 (2020); Ilana G. Dzuba et al., *A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64–70 days and 71–77 Days of Gestation*, 101 Contraception 302 (2020).

pregnancy experience sharp, severe and typically unilateral lower abdominal pain that differs from the more midline cramping and discomfort medication abortion patients often experience. Again, this is why the Protocol includes educating patients about what to expect during a medication abortion, signs and symptoms more associated with ectopic pregnancy and detailed information about what signs or symptoms should prompt immediate evaluation in an emergency department, and recommends close follow up with patients to ensure that the abortion was completed.

54. Finally, both Dr. Wubbenhorst and Dr. Bane criticize the practice of no-touch ectopic screening and my research showing that use of an ultrasound to rule out an ectopic pregnancy is not medically indicated for most patients. *See* Wubbenhorst Decl. ¶¶ 394-407; Bane Decl. ¶ 60. Contrary to their claims, no-touch screening does not "disregard[]" the seriousness of ectopic pregnancy, and I do not provide medication abortion to patients without assessing gestational age and evaluating for ectopic pregnancy, as Dr. Wubbenhorst suggests. Wubbenhorst Decl. ¶¶ 395, 398. Rather, as discussed above, research and my personal experience have shown that, after thorough screening conversations with patients and trusting that a patient is the most informed person about their own body, it is safe to provide medication abortion to patients whom a physician has determined to be at a low risk for an ectopic pregnancy.[66]

[66] *See* Ushma D. Upadhyay, Christy Boraas (2022), *supra* note 58; Holly A. Anger, Christy Boraas et al., *Clinical and Service Delivery Implications of Omitting Ultrasound Before Medication Provided Abortion via Direct-To-Patient Telemedicine and Mail in the U.S.*, 104 Contraception 659 (2021).

55. If a patient is not determined to be low risk, it would not be appropriate to go forward with a medication abortion, and the patient would be counseled to seek further assessment to determine whether they have an ectopic pregnancy. To be clear, if a patient is determined to be at risk for an ectopic pregnancy, medication abortion is not prescribed.

56. Dr. Bane cites the 2018 ACOG Bulletin to support her position that ultrasounds are required for ectopic evaluation. Bane Decl. ¶ 60. The Bulletin states that "the minimum diagnostic evaluation of a *suspected* ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."[67] I agree—if an ectopic pregnancy is suspected, ultrasonography is required to ultimately determine the location of the pregnancy. However, if a patient is determined to be low risk—i.e., an ectopic pregnancy is *not suspected*—then ultrasound confirmation of an intrauterine pregnancy is not required before administration of medication abortion in accordance with the Protocol.

57. The safety of my patients is my top priority. As research and my personal experience have shown, with the proper protocol, counseling, surveillance, and follow-up, medication abortion may be safely and effectively administered to low-ectopic-risk patients with pregnancies of unknown location who prefer that method of treatment. Thus, there is no medical reason to require the confirmation of an intrauterine pregnancy before administering medication abortion.

[67] ACOG, *Tubal Ectopic Pregnancy*, 131 Obstetrics & Gynecology e65, e66 (2018) (emphasis added).

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58. In sum, the Hospitalization Requirement and IUP Documentation Requirement impede patient access to care and do not improve patient safety. My opinion is supported by the research cited above, by my education and clinical training, and by my own experiences. Abortion is a critical component of reproductive health care. Nothing in the declarations of Dr. Wubbenhorst and Dr. Bane alters the conclusions I reached or the opinions I expressed in my prior declaration. Instead, Dr. Wubbenhorst's and Dr. Bane's declarations include false and misleading information and inflammatory language that serves only to perpetuate the harmful stigma surrounding abortion.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 18, 2023

Christy M. Boraas Alsleben, M.D., M.P.H.